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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,287	02/03/2005	Kenji Kogami	SAEG122.002APC	3585

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

HAVLIN, ROBERT H

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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10/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No. 10/523,287	Applicant(s) KOGAMI ET AL.	
	Examiner ROBERT HAVLIN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8 and 10-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-8, 10-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/14/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE: A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/17/09 has been entered.

Status of the Claims: Claims 1, 2, 4-8 10-17 are currently pending.

Declarations

1. The declaration of Kenji Kogami under 37 CFR 1.132 filed 7/14/09 was considered. A discussion of the relevance of this declaration to the rejection of the claims based upon 35 USC 103 is discussed below.

RESPONSE TO APPLICANT ARGUMENTS

Claim Rejections - 35 USC § 103

2. Claims 1-2 were rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (Chirality, 12:26-29 (2000) in IDS) in view of Makarova et al. (Russian Journal of General Chemistry, Vol. 71, No. 7, 2001, pp. 1126-1129.), Gribble et al. (Org. Prep. Proc. Int. v. 17, p. 317-384 (1985)) and March (March's Advanced Organic Chemistry, 5th ed. (2001), Wiley, p. 2083).

Applicant has provided the declaration of Kogami showing that the reduction of the compound does not proceed without the presence of the carboxylic acid. This evidence is persuasive as to the unpredictable nature of the type of reduction reaction

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applicant claims. In addition, review of the Gribble reference as pointed out by applicant also shows that there is some degree of unpredictability regarding which groups will be reduced under the various conditions discussed. Thus, applicant's arguments as to the nonobviousness of the claims are persuasive and the rejection is **withdrawn**.

3. Claims 4-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (Chirality, 12:26-29 (2000) in IDS) in view of Makarova et al. (Russian Journal of General Chemistry, Vol. 71, No. 7, 2001, pp. 1126-1129.). Based on the discussion above the rejection is **withdrawn**.

4. Claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (Chirality, 12:26-29 (2000) in IDS) in view of Makarova et al., Wright et al. (Journal of Medicinal Chemistry (1992), 35(22), 4061-8) and Guseinov et al. (CASREACT abstract # 122:132250 of Zhurnal Organicheskoi Khimii (1994), 30(4), 496-9). Based on the discussion above the rejection is **withdrawn**.

5. Claims 7 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (Chirality, 12:26-29 (2000) in IDS) in view of Makarova et al., Gribble et al. (Org. Prep. Proc. Int. v. 17, p. 317-384 (1985)), March (March's Advanced Organic Chemistry, 5th ed. (2001), Wiley, p. 2083), and Makarova-2 (Russian Journal of General Chemistry, Vol. 37, No. 8, 2001, pp. 1099-1101.). Based on the discussion above the rejection is **withdrawn**.

Double Patenting

6. Claims 4 and 5 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-2 of copending Application No. 11/989100.

In response, applicant requests that the issue be deferred until the application is otherwise in condition for allowance. Therefore, **this rejection is maintained.**

NEW CLAIM REJECTIONS

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 4-5 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,984,738.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

US 6,984,738 teaches 3-methylamino-thiophen-2-yl-propenone which anticipates the claims.

9. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

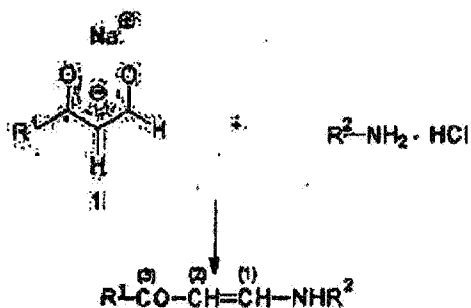
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Chatterjee et al. (Cited in the 7/14/09 IDS).

1. *Determining the scope and contents of the prior art.*

Chatterjee teaches the following method:

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on page 253. The method is described to

include R¹ as thiophen-2-yl and the R² substituents vary among members including phenyl and substituted alkyl.

2. *Ascertaining the differences between the prior art and the claims at issue.*

The difference between the prior art and the claims is the substitution at the R² position.

3. *Resolving the level of ordinary skill in the pertinent art.*

One of ordinary skill in the art would consider routine and well within their technical grasp the process of altering reactions taught with similar groups and applying those reaction conditions in other contexts.

4. *Considering objective evidence present in the application indicating obviousness or nonobviousness.*

The application does not contain any secondary considerations with respect to the claim.

The Supreme Court stated in *KSR* "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007).

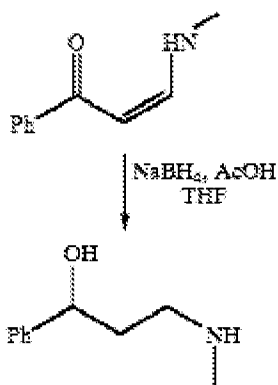
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In this case, the technique was previously demonstrated to work in one context and one of ordinary skill in the art would expect it would operate in the same way in other closely related contexts. Thus based on the similarity of the R2 groups one of ordinary skill in the art would have an expectation that the reaction would work equally well if R2 was only C1-4-alkyl. Therefore, **the claims are rejected**.

13. Claims 1, 2, 4-8, 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zelenin (US 6,846,957 and US 2004/0102651) in view of Yokozawa et al. (US 6,984,738).

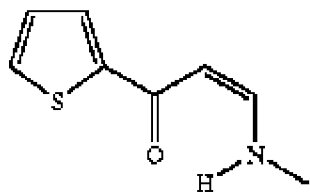
1. *Determining the scope and contents of the prior art.*

Zelenin teaches the following method (in col 5):



useful for the production of pharmaceuticals and cites to the method of making products as described by Chatterjee above.

Yokozawa teaches as described above the motivation to make the product



useful for the production of pharmaceuticals.

2. *Ascertaining the differences between the prior art and the claims at issue.*

The difference between the prior art and the claims is the substitution of phenyl for 2-thienyl and the solvent used.

3. *Resolving the level of ordinary skill in the pertinent art.*

One of ordinary skill in the art would consider routine and well within their technical grasp the process of altering reactions taught with similar groups and applying those reaction conditions in other contexts.

4. *Considering objective evidence present in the application indicating obviousness or nonobviousness.*

The application does not contain any secondary considerations with respect to the claim.

The Supreme Court stated in *KSR* "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *KSR Intern. Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731 (2007).

In this case, the technique was previously demonstrated to work in one context and one of ordinary skill in the art would expect it would operate in the same way in other closely related contexts. Thus based on the similarity of the chemical groups one of ordinary skill in the art would have an expectation that the reaction would work equally well if phenyl were replaced with a group such as 2-thienyl. Therefore, **the claims are rejected.**

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claim 6, 14, and 15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 and 6 of copending Application No. 11/989100. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the ‘100 application recite a method that anticipates the instant claims or would have been obvious to one of ordinary skill in the art. Claims 14 and 15 specifically recite the use of particular salt forms which one of ordinary skill in the art would find to be obvious in view of the finite predictable options available for providing a primary amine for a reaction.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The claims are not in condition for allowance.

The examiner would like to cite the following references as relevant prior art:

- Johnson and Rickborn, Sodium borohydride reduction of conjugated aldehydes and ketones, J. Org. Chem., 1970, 35 (4), 1041-1045.
- Nutaitis and Bernardo, Regioselective 1,2-reduction of conjugated enones and enals with sodium monoacetoxymethylborohydride: preparation of allylic alcohols, J. Org. Chem., 1989, 54 (23), 5629-5630.
- Andrews and Mosbo, Syntheses of .beta.-diamines and .beta.-amino alcohols from .alpha.,.beta.-unsaturated ketones and aldehyde, methylamine, and borohydride reducing agents, J. Org. Chem., 1977, 42 (4), 650-652.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626